HAP CareSource™

PHARMACY POLICY STATEMENT
HAP CareSource™ Marketplace

DRUG NAME	Symdeko (tezacaftor/ivacaftor)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Symdeko, approved by the FDA in 2018, is a combination of tezacaftor and ivacaftor, indicated for the treatment of cystic fibrosis (CF) in patients aged 6 years and older who are homozygous for the F508del mutation or who have at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to tezacaftor/ivacaftor based on in vitro data and/or clinical evidence. Cystic fibrosis is an autosomal recessive disease in which patients can have abnormal airways secretions, chronic endobronchial infection, and progressive airway obstruction.

Symdeko (tezacaftor/ivacaftor) will be considered for coverage when the following criteria are met:

Cystic Fibrosis

For **initial** authorization:

1. Member is at least 6 years of age; AND
2. Medication must be prescribed by or in consultation with a pulmonologist or an infectious disease specialist; AND
3. Member has a diagnosis of cystic fibrosis; AND
4. Member has had genetic testing documented in chart notes with two copies (homozygous) of the F508del mutation (F508del/F508del) in their CFTR gene; OR
5. Member has at least **ONE** of the following mutations in the CFTR gene: 546insCTA, E92K, G576A, L346P, R117G, S589N 711+3A→G, E116K, G576A;R668C, L967S, R117H, S737F 2789+5G→A, E193K, G622D, L997F, R117L, S912L, 3272-26A→G, E403D, G970D, L1324P, R117P, S945L, 3849+10kbC→T, E588V, G1069R, L1335P, R170H, S977F, A120T, E822K, G1244E, L1480P, R258G, S1159F, A234D, E831X, G1249R, M152V, R334L, S1159P, A349V, F191V, G1349D, M265R, R334Q, S1251N, A455E, F311del, H939R, M952I, R347H, S1255P, A554E, F311L, H1054D, M952T, R347L, T338I, A1006E, F508C, H1375P, P5L, R347P, T1036N, A1067T, F508C;S1251N, I148T, P67L, R352Q, T1053I, D110E, F508del, I175V, P205S, R352W, V201M, D110H, F575Y, I336K, Q98R, R553Q, V232D, D192G, F1016S, I601F, Q237E, R668C, V562I, D443Y, F1052V, I618T, Q237H, R751L, V754M, D443Y;G576A;R668C, F1074L, I807M, Q359R, R792G, V1153E, D579G, F1099L, I980K, Q1291R, R933G, V1240G, D614G, G126D, I1027T, R31L, R1066H, V1293G, D836Y, G178E, I1139V, R74Q, R1070Q, W1282R, D924N, G178R, I1269N, R74W, R1070W, Y109N, D979V, G194R, I1366N, R74W;D1270N, R1162L ,Y161S, D1152H, G194V, K1060T, R74W;V201M, R1283M, Y1014C, D1270N, G314E, L15P, R74W;V201M;D1270N, R1283S, Y1032C, E56K, G551D, L206W, R75Q, S549N, E60K, G551S, L320V, R117C, S549R.

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6. **Dosage allowed/Quantity limit:** Quantity limit: 56 tablets per 28 days.

Age	Morning (one tablet)	Evening (one tablet)
6 to <12 years weighing <30 kg	tezacaftor 50 mg/ivacaftor 75 mg	ivacaftor 75 mg
6 to <12 years weighing ≥30 kg	tezacaftor 100 mg/ivacaftor 150 mg	ivacaftor 150 mg
≥12 years	tezacaftor 100 mg/ivacaftor 150 mg	ivacaftor 150 mg

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:

1. Chart notes must show improvement or stabilized signs and symptoms of disease demonstrated by any of the following:

a) Improved FEV1 and/or other lung function tests;
b) Improvement in sweat chloride;
c) Decrease in pulmonary exacerbations;
d) Decrease in pulmonary infections;
e) Increase in weight-gain;
f) Decrease in hospitalizations.

If all the above requirements are met, the medication will be approved for an additional 12 months.

HAP CareSource considers Symdeko (tezacaftor/ivacaftor) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
02/27/2018	New policy for Symdeko created.
12/31/2020	Age changed to 6 years old and older (previously only approved for patients 12 years and older). Added approved mutations based on new FDA approvals. Diagnosis of cystic fibrosis added to initial criteria. Changed status to Preferred. Removed requiring trials of Orkambi and Kalydeco. Reauthorization criteria updated to ask for evidence of disease improvement.
05/18/2022	Policy for Symdeko transferred to new template. Added pediatric dosing.
01/30/2025	Increased initial authorization length from 3 months to 6 months; removed adherence and compliance with initial criteria from reauthorization criteria.

References:

1. Symdeko [package insert]. Boston, MA: Vertex Pharmaceuticals Incorporated; 2025.
2. Ren CL, Morgan RL, Oermann C, et al. Cystic Fibrosis Foundation Pulmonary Guidelines. Use of Cystic Fibrosis Transmembrane Conductance Regulator Modulator Therapy in Patients with Cystic Fibrosis. *Ann Am Thorac Soc.* 2018;15(3):271-280. doi:10.1513/AnnalsATS.201707-539OT
3. Farrell PM, White TB, Ren CL, et al. Diagnosis of Cystic Fibrosis: Consensus Guidelines from the Cystic Fibrosis Foundation [published correction appears in J Pediatr. 2017 May;184:243]. J Pediatr. 2017;181S:S4-S15.e1. doi:10.1016/j.jpeds.2016.09.064.
4. Southern KW, Castellani C, Lammertyn E, et al. Standards of care for CFTR variant-specific therapy (including modulators) for people with cystic fibrosis. J Cyst Fibros. 2023;22(1):17-30. doi:10.1016/j.jcf.2022.10.002

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Revised date: 01/30/2025